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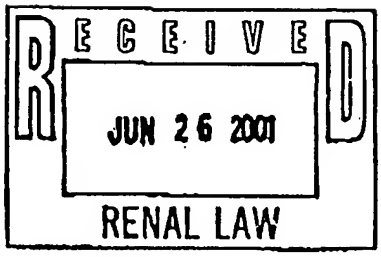
European Patent No. 0 956 876 A1



Job No.: 1084-83477 Ref.: DISPOSABLE CASSETTE & IN-LINE HEATING
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CASSETTE FOR CONVEYING FLUIDS, ESPECIALLY DIALYSIS FLUIDS

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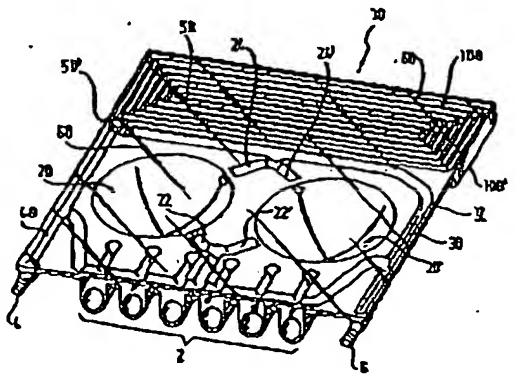
The present invention pertains to a cassette (10) for conveying fluids, especially dialysis fluids, with connector elements (2,4,6) for connecting solution bags and lines leading to the patient or the dialysis machine, with at least one conveyor chamber (20,20') with inlet and outlet (22,22',24,24'), with lines (30,40,50,50') for carrying the introduced and conveyed fluids, while the walls of the lines (30,40,50,50') are at least sectionally so designed that said lines (30,40,50,50') can be closed by applying pressure thereto. Heating of the fluids is possible in that an area is provided inside the cassette that can be heated by a heating device outside the cassette.

The invention further pertains to a dialysis machine, especially for accomplishing peritoneal dialysis and blood and plasma filtration procedures, with a device for holding a cassette (10) according to the invention as well as a pump unit for actuating the conveyor chambers (20, 20'). Contained within the dialysis machine is a heating device, which is located in the vicinity of the device for holding the cassette (10).



Description

[0001]

The present invention pertains to a cassette for conveying fluids, especially dialysis fluids, with connector elements for connecting solution bags and lines leading to the patient or the dialysis machine, with at least one conveyor chamber with inlet and outlet and with lines for carrying the introduced and displaced fluids, while the walls of the lines are at least sectionally so designed that said lines can be closed by applying pressure thereto. The present invention further pertains to a dialysis machine for holding the cassette for conveying fluids, especially dialysis fluids, as well as a process for conveying, equalizing, dosing and heating a medicinal fluid.

[0002]

Generic cassettes for conveying fluids, especially dialysis fluids, are known from WO 97/09074 and are routinely used as exchangeable articles in dialysis machines. Here the cassettes fulfill the function of a medium-separated conveyor of the dialysis fluid. The conveyor chamber in the cassette is pneumatically driven by a competent drive unit of the dialysis machine. The employment of a mechanically or hydraulically driven conveyor chamber is also possible. The conveyor chamber has a membrane, which is moved by the drive unit and ensures a separation between the media to be displaced and the working medium of the dialysis machine. Regulation of the flow of the fluid in the cassette is accomplished by means of pneumatically controlled valves. In order to heat the dialysis fluid to the desired temperature for delivery to the patient and to maintain it at this level to the patient, WO 97/09074 discloses trays on which the solution bags are placed during the dialysis. The trays are heated, e.g., by heating cartridges that are themselves regulated by a control unit.

[0003]

With such an arrangement it is disadvantageous that the heating of the dialysis fluids is not uniform due to the one-sided positioning on the heating trays and is associated with considerable loss of heat. Furthermore, a separately provided heating stage is necessary, which commensurately increases the cost of the dialysis machine.

[0004]

It is the objective of the present invention to create a device with which the heating and the delivery of fluids, especially dialysis fluids, can be effectively and simply accomplished.

[0005]

Proceeding from a cassette of the generic type, this objective is realized in that at least one area is provided in the cassette, in which the lines are so arranged that the medium contained in the lines can be heated to a predetermined desired temperature by a heating device located outside the cassette. The cassette according to the invention has the advantages that the component tasks of delivery, dosing/equalizing, mixing, metering, correcting and heating of medicinal fluids are combined or can be resolved in one unit. This results in a significant relief in the operating of the system and an improvement of the prevention of errors due to minimalization of the risk-related working steps. The thoroughly medium-separated connection of the cassette according to the invention permits a sterile conduct of the procedure and thus reliably eliminates the danger of infection.

[0006]

According to one preferred configuration of the present invention, the cassette encompasses a basic body as well as one or more films at least partially covering the basic body, which are joined to the basic body, while the walls of the lines and the conveyor chambers are formed by the basic body and the films. In the area of the conveyor chambers, the appropriately expanded film serves as the membrane, which is moved in the conveyor chamber by a piston pump, e.g., in keeping with the desired rate of delivery. The lines of the cassette, which serve to direct the flow of the fluid, are also delimited by the basic body and the film covering it. Here it is possible that only one wall of the lines, or also several walls, [is/]are formed by films.

[0007]

An additional configuration of the present invention provides that the film extends on both sides of the basic body. This is particularly advantageous in the area of the cassette in which the lines are so arranged that the medium in the lines can be heated to a prescribed desired temperature by a heating device located outside the cassette. In this case it is possible, commensurate with the two-sided use of the film, for both sides of the cassette and therefore the medium flow being displaced to be effectively heated.

[0008]

It is especially advantageous when one side of the basic body is completely covered with a film. In this case the film serves as an elastic membrane in the area of the conveyor chambers, which, on the one hand, effects the delivery of the dialysis fluid, e.g., and on the other hand, facilitates a separation of the media. In the area of the lines, the film forms one of the walls and makes possible an especially favorable and effective transfer of heat to the medium inside the line.

[0009]

The production of the cassette is also simplified in this case, since the basic body merely has depressions or recesses for forming the conveyor chambers and is ultimately lined with a film according to the invention, whereby the depressions are converted into conveyor chambers and the channels in the basic body become lines. The film can be comparatively simply applied by molding or gluing onto the basic body.

[0010]

According to one preferred configuration of the present invention, two conveyor chambers are provided. Then it is possible, with alternating actuation of the conveyor chambers by an appropriately attuned drive unit, to achieve a relatively uniform flow through the cassette and to the dialysis machine and the patient. It is equally possible, with appropriate separation of the conveyor chambers, for one of the conveyor chambers to be used for the high pressure range and another, e.g., for the vacuum or low pressure range. Both conveyor chambers can be delimited by the basic body in the cassette as well as by the film applied thereto. Control of the flow of the medium through the cassette or a comparable activation of the conveyor chambers is achieved according to the invention in that the walls of the lines are at least sectionally designed so that the lines can be closed by applying pressure to the walls. This pressure can be applied, e.g., pneumatically or mechanically by means of valve tappets.

[0011]

In an additional configuration of the present invention, provision is made for the lines to be arranged spirally at least in the heatable part of the cassette. This results in the advantage that a relatively large length of line is arranged in a comparatively small area of the cassette, which permits an especially effective heating of the medium in the lines. In addition to a spiral arrangement, other configurations are conceivable, which are always especially effective when the ratio of the length of the line to the space required therefore increases, similarly when a turbulent flow is realized even with lower rates of flow.

[0012]

It is particularly advantageous when areas with spirally arranged lines extend along both sides of the basic body. This makes it possible for the fluid to be heated on one side of the cassette using an appropriately arranged heating device and for it then to be held at the desired temperature on the other side or heated further as required.

[0013]

The areas on different sides of the basic body can be connected together with a bore located in the basic body. Then it is possible for the media to be initially directed to one side of the basic body and heated and then passed through the bore to the other side and further heated, which is especially effective when the lines on both sides are spirally arranged.

[0014]

According to a preferred configuration of the present invention, the basic body consists at least in part of plastic. The fabrication of the basic body from plastic has the advantage that it can be produced, e.g., by injection molding simply and especially in many conceivable designs.

[0015]

It is especially advantageous when the basic body is equipped with holders for mounting measurement recorders, in particular holders for mounting sensors for temperature and pressure as well as flow rate can be mounted on the basic body. For example, the temperature sensors can determine the temperature of the dialysis solution inside the film and relay the readings to an evaluation unit. For regulating to a desired temperature range, either the delivery rate through the heated lines or the heat output at constant delivery rates can be varied.

[0016]

According to one preferred configuration of the present invention, a line leading to the patient and a drainage tube are provided, which are permanently connected to the cassette. This cassette is fabricated with these lines, while the installation of the other connected elements is decided and accomplished by the operator in agreement with the dialysis procedures ordered.

[0017]

The invention further pertains to a dialysis machine, especially for accomplishing peritoneal dialysis and blood and plasma filtration procedures, with a recess or a device for holding a cassette according to one or more of Claims 1-10 as well as a pump unit for actuating the conveyor chambers of the cassette. For heating the cassette according to the invention a heating device is provided, which is located in the vicinity of the recess or device for holding the cassette. According to the invention, it is then always possible to use a new cassette for each patient, which [cassette] is inserted into the dialysis machine or mounted thereon in an appropriate manner. The medium-separated connection of the cassette to the dialysis machine makes possible sterile conduct of the procedure and ensures aseptic conditions even when the dialysis machine is used for several patients. Danger of infection is thus effectively precluded, so that the cassette is advantageously designed to be disposable and not suitable for reuse following one-time utilization.

[0018]

Altogether, a simple, reliable and effective dialysis system results, in which the operator, following input of the desired reference values, must merely position the cassette in the recess or

the device provided therefore and connect the necessary lines. A separate arrangement of heating devices or elements is not necessary.

[0019]

In an additional configuration of the present invention, provision is made for the heating device to have electric conductive sheet-type heating elements. This is especially advantageous when the cassette has flat surfaces containing, e.g., spirally arranged lines. In this case, an especially effective heating of the media flowing through the lines is possible.

[0020]

The heating device can extend on both sides of the recess or device for holding the cassette, so that the cassette is heatable on both sides. In this case, an effective heating of the media to the desired temperature can be realized in relatively little space even at high flow rates.

[0021]

The present invention also pertains to a procedure for conveying, equalizing, metering and heating a medicinal fluid, in which a fluid is fed through lines and at least one conveyor chamber and simultaneously charged with thermal energy. This provides a process that is simple to carry out, in which, e.g., the component tasks of delivery, dosing/equalizing, mixing, metering, connecting and heating of medicinal fluids can be combined or resolved in a compact manner.

[0022]

It is especially advantageous when the fluid is first passed through the conveyor chambers and then heated in an area encompassing the lines. However, it is also possible for the heating to take place first or exclusively in the conveyor chambers. The heating of the fluid in the lines has the advantage that with favorable arrangement of the lines in a comparatively small area a great length of the lines can be realized. This makes it possible for the fluid to be purposefully and effectively heated even with high flowthrough rates.

[0023]

The heating can take place in an area where the lines are spirally arranged. This results in an especially favorable ratio of line length per unit of area, wherewith an especially effective heating is possible.

[0024]

In an additional configuration of the invention, provision is made for the fluid to be first passed through at least the single conveyor chamber of a cassette provided for the delivery, equalization, metering and heating of the fluid, then heated in lines on one side of the cassette and moved to the other side of the cassette and again heated in lines located there. This makes it possible, by virtue of the relatively great length of the lines extending on both sides of the cassette in such an arrangement, to achieve an adequate heating of the fluid even at high flowthrough rates.

[0025]

Additional advantages and details of the present invention are explained in greater detail with references to an embodiment example illustrated in the drawing. This depicts:

Figure 1, a perspective illustration of a cassette according to the invention with two conveyor chambers and with areas for heating the conveyed fluid.

[0026]

Figure 1 depicts the cassette (10) according to the invention, which is designed to be disposable and can be inserted into an appropriately configured recess or receiver of a dialysis machine. The reference numbers (2,4,6) identify connector elements for connecting solution bags and lines leading to the patient or the dialysis machine or also drainage lines. Securely connected at the connectors (4) and (6) are two (undepicted) lines, of which one represents the line to the patient and the other the drainage line. The connector elements (2) are for the connections to be made by the operator, e.g., from solution bags or other medication containers.

[0027]

The cassette (10) encompasses the basic body (12), which is made of plastic and can be fabricated in the injection molding or the deep-draw process. Extending in the basic body (12) are recesses and channels, which partially form the walls of the two side-by-side conveyor chambers (20,20') as well as the lines (30,40,50,50') located in the cassette. The lines leading out from the connector elements (2) as well as the inlets (22,22') and the outlets (24,24') of the conveyor chambers (20,20') are also formed in part by the basic body (12).

[0028]

Above the side of the basic body (12) depicted in Figure 1 and extending over the entire surface is a film (60), which is molded onto the basic body (12). The film (60) forms the limits of the channels and depressions formed in the basic body (12), whereby, e.g., the lines

(30,40,50,50') and the conveyor chambers (20,20') are also delimited. The inlets (22,22') and the outlets (24,24') of the conveyor chambers (20,20') are also delimited by the film (60) on one side.

[0029]

In the areas (100,100') indicated above the conveyor chambers (20,20') in Figure 1, the lines (50,50') are so arranged that the medium inside the lines (50,50') can be heated to a predetermined desired temperature by a heating device outside the cassette (10). Here the lines (50,50') extend along both the upper side (lines 50) and the lower side (lines 50') shown in Figure 1.

[0030]

The control of the introduced or conveyed media is accomplished in such a way that the walls, e.g., of the lines (30, 40, 50, 50') as well as the inlets (22, 22') and the outlets (24, 24') of the conveyor chambers (20,20') can be closed by applying pressure to the walls. This pressure can be applied, e.g., pneumatically, hydraulically or mechanically by valve tappets, which are activated by a control unit of the dialysis machine.

[0031]

The connection of solution bags and other medication containers is made at the connector elements (2) shown in Figure 1, which also have a contact protector. With appropriate valve settings, the introduced media are fed via the inlets (22,22') into the conveyor chambers (20,20') and then pumped out of the conveyor chambers (20,20') by the movement of the film (60) effected by the drive unit of the dialysis machine. This takes place through the outlets (24,24') which come together and then open into a first section of the line (50). The conveyed medium then flows through the line (50) in the area (100) on the upper side and is there heated by a conveniently located heating device of the dialysis machine. In the end section of the spiral line (50) there is an (undepicted) bore that forms a connection to the area (100') on the lower side of the basic body (12). Accordingly, the medium flows through this bore to the other side of the basic body (12) and into the spiral line (50'), where further heating can take place. Subsequently, the heated fluid leaves the cassette (10) of the invention via connector (4) or the line connected thereto and makes its way to the patient or the dialysis machine.

[0032]

The cassette according to the invention and the dialysis machine according to the invention are suitable for use in peritoneal dialysis as well as in blood and plasma filtration.

Commensurately, employment in peritoneal systems and systems with extracorporeal blood circulation is possible.

[0033]

The geometry of the lines according to Figure 1 facilitates a simple control of the media by closing the lines, e.g., with connected valve tappets, whereby flawless functioning is made possible in both the upper and the lower pressure ranges. Heating of the areas (100,100') ensues on both the upper and the lower sides by means of (e.g., ohmic) electric conductive sheet-type heating elements. The geometry of the lines (50,50') is specially optimized for a good heat transfer with simultaneously low valve losses. Despite high surface power density (e.g., approximately 5 W/cm^2), the surface temperatures of the heating elements remain low (<100°C). This keeps the demands of the temperature stability of the film (60) and the basic body (12) low.

[0034]

In automatic peritoneal dialysis, the lines (40) and (30) can be used, e.g., for fresh dialysis solutions or for used dialysate.

[0035]

With the combination of medium-separated delivery characteristics and the favorable heating characteristics, the cassette or the dialysis machine according to the invention can be used to advantage in automatic peritoneal dialysis (APD) and in diverse blood and plasma filtration procedures (universal HDF [hemodiafiltration], CVVHF [continuous veno-venous hemofiltration], CVVHDF [continuous veno-venous hemodiafiltration], PF [plasma filtration], etc.) as well as in adsorber applications with extracorporeal blood circulation.

Claims

1. Cassette (10) for conveying fluids, especially dialysis fluids,

with connector elements (2,4,6) for connecting solution bags and lines leading to the patient or the dialysis machine;

with at least one conveyor chamber (20,20') with inlet and outlet (22,22',24,24');

with lines (30,40,50,50') for carrying the introduced and conveyed fluids, while the walls of the lines (30,40,50,50') are at least sectionally so designed that said lines (30,40,50,50') can be closed by applying pressure to the walls, characterized in that

at least one area (100,100') is provided in the cassette (10), in which the lines (50,50') are so arranged that the medium inside the lines (50,50') can be heated to a predetermined desired temperature by a heating device outside the cassette (10).

2. Cassette (10) according to Claim 1, characterized in that the cassette (10) encompasses a basic body (12) and one or more films (60) molded onto and at least partly covering the basic body (12), while the walls of the lines (30,40,50,50') and the conveyor chambers (20,20') are formed by the basic body (12) and the films (60).

3. Cassette (10) according to Claim 2, characterized in that the film (60) extends on both sides of the basic body (12).

4. Cassette (10) according to Claim 2 or 3, characterized in that one side of the basic body (12) is completely covered with a film (60).

5. Cassette (10) according to one or more of Claims 1-4, characterized in that two conveyor chambers (20,20') are provided.

6. Cassette (10) according to one or more of Claims 1-5, characterized in that the lines (50,50') are spirally arranged at least in the heatable area (100,100').

7. Cassette (10) according to Claim 6, characterized in that areas (100,100') with spirally arranged lines extend along both sides of the basic body (12).

8. Cassette (10) according to Claim 7, characterized in that the areas (100,100') on different sides of the basic body (12) are connected by a bore in the basic body (12).

9. Cassette (10) according to one or more of Claims 2-8, characterized in that the basic body (12) consists at least in part of plastic.

10. Cassette (10) according to one or more of Claims 2-9, characterized in that the basic body (12) has holders for mounting measurement recorders.

11. Cassette (10) according to one or more of Claims 1-10, characterized in that a line leading to the patient and a drainage line are provided, which are permanently connected to the cassette (10).

12. Dialysis machine for accomplishing peritoneal dialysis and blood and plasma filtration procedures, with a recess or device for holding a cassette (10) according to one or more of Claims 1-10 and with a pump unit for actuating the conveyor chambers (20,20') of the cassette (10), characterized in that

a heating device is provided, which is located in the vicinity of the recess or device for holding the cassette (10).

13. Dialysis machine according to Claim 12, characterized in that the heating device has electric conductive sheet-type heating elements.

14. Dialysis machine according to Claim 12 or 13, characterized in that the heating device extends on both sides of the recess or device for holding the cassette (10) in such a way that the cassette (10) can be heated on both sides.

15. Process for conveying, equalizing, metering and heating a medicinal fluid, characterized in that

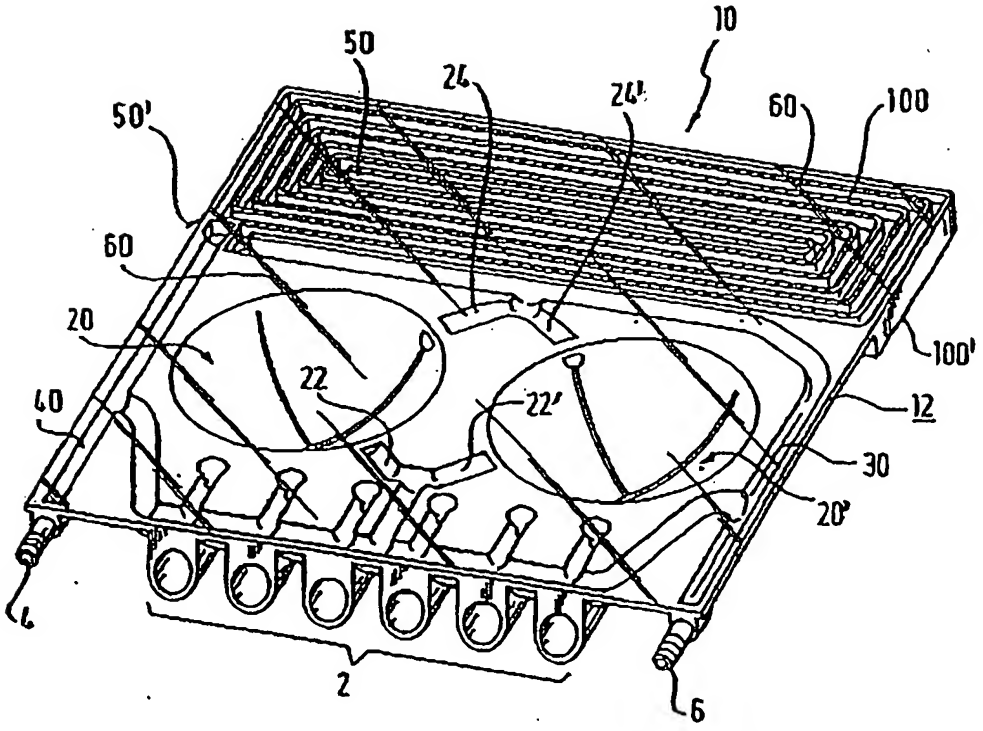
a fluid is fed through lines (30,40,50,50') and at least one conveyor chamber (20,20') and is simultaneously charged with thermal energy.

16. Process according to Claim 15, characterized in that the fluid is first passed through the conveyor chambers (20,20') and then heated in an area (100,100') containing lines (50,50').

17. Process according to Claim 16, characterized in that the heating takes place in an area (100,100'), in which the lines (50,50') are spirally arranged.

18. Process according to one or more of Claims 15-17, characterized in that the fluid is first passed through at least one conveyor chamber (20,20') of a cassette (10) provided for the delivery, equalization, metering and heating of the fluid and then heated in lines (50) located on one side of the cassette (10), whereupon a transfer of the fluid to the other side of the cassette (10) and further heating in lines (50') located on this side of the cassette (10) ensue.

Fig. 1



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Application No. EP 99 10 5771

EUROPEAN SEARCH REPORT

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.[6])
X	EP 0 687 474 A (FRESENIUS AG) December 20, 1995 (1995-12-20) * Column 3, line 57 – column 4, line 6 * * Column 4, line 29 - line 58 * * Column 5, line 45 – line 58 * * Column 6, line 14 – line 25 * * Column 9, line 13 – line 42 * * Figure 1 *	1,5,12,15	A61M5/44
A	EP 0 482 858 A (ALCON SURGICAL INC) April 29, 1992 (04-29-1992) * Column 5, line 17 – column 6, line 29; Figure 1 *	1,2,4,6,9, 10,15-17	
			TECHNICAL FIELDS SEARCHED (Int. Cl.[6])
			A61M

The present search report has been drawn up for all claims.

Place of search	Date of completion of the search	Examiner
THE HAGUE	July 20, 1999	Lakkis, A

CATEGORY OF CITED DOCUMENTS

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D: Document cited in the application.
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APPENDIX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 99 10 5771

In this appendix, the patent family members of patent documents listed in the above-referenced European Search Report are indicated.

The data on the family members correspond to the state of the files of the European Patent Office on July 20, 1999

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Patent document listed in the search report		Date of publication	Member(s) of the patent family		Date of publication
EP 0687474	A	December 20, 1995	DE	4421126 A	December 21, 1995
			JP	8164201 A	June 25, 1996
			US	5542919 A	August 6, 1996
EP 0482858	A	April 29, 1992	AU	8674191 A	April 30, 1992
			CA	2054233 A	April 27, 1992
			WO	9207611 A	May 14, 1992

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